

Decision Memo for Urine Culture (Bacterial) and Serum Iron Studies (Revision of ICD-9-CM Codes for Pre-operative Examinations) (CAG-00236N)

Decision Summary

CMS has determined that ICD-9-CM code V72.84, Pre-operative examination, unspecified, does not flow from the narrative indications in the national coverage determination (NCD) for urine culture and serum iron studies. We have concluded that the code was placed on the list of "ICD-9-CM Codes Covered by Medicare" erroneously. We intend to remove it in an upcoming modification of the laboratory edit module for implementing the negotiated laboratory NCDs.

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Decision Memo

This coding analysis does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue a change to the list of ICD-9-CM Codes Covered that are linked to two of the negotiated laboratory NCDs. This decision will be announced in an upcoming recurring update notification in accordance with CMS Pub 100-4, Chapter 16, section 120.2 and will become effective as of the date listed in the transmittal that announces the revision.

TO: Administrative File: CAG-00236N Urine Culture and Serum Iron Studies (Revision of ICD-9-CM Codes for Pre-operative Examinations)

FROM:

Steve Phurrough, MD, MPA
Director, Coverage and Analysis Group

Louis Jacques, MD
Director, Division of Items and Devices
Coverage and Analysis Group

Jackie Sheridan-Moore
Technical Advisor, Division of Items and Devices
Coverage and Analysis Group

RE: Decision Memorandum for Coding Analysis of Urine Culture and Serum Iron
Studies for Pre-operative Examinations

DATE: July 26, 2004

I. Decision

CMS has determined that ICD-9-CM code V72.84, Pre-operative examination, unspecified, does not flow from the narrative indications in the national coverage determination (NCD) for urine culture and serum iron studies. We have concluded that the code was placed on the list of "ICD-9-CM Codes Covered by Medicare" erroneously. We intend to remove it in an upcoming modification of the laboratory edit module for implementing the negotiated laboratory NCDs.

II. Background

On June 15, 2004 CMS began a coding analysis for re-evaluation of ICD-9-CM code V72.84 in the list of "ICD-9-CM Codes Covered by Medicare" associated with the urine culture and serum iron studies NCDs. The codes on this list are intended to flow from the narrative indications for coverage as stated in the NCDs. We have previously reviewed the issue of inclusion of this code in the list of covered services for prothrombin time (PT) and partial thromboplastin time (PTT) tests. (See cms.hhs.gov/mcd/viewdecisionmemo.asp?id=93.) We concluded that it is not appropriate under the Medicare statute to include codes for routine screening services in the list of covered codes for PT and PTT. In the decision memorandum for this issue, we noted that we would also reconsider the inclusion of V72.84 in the list of covered codes for urine culture and serum iron studies.

III. History of Medicare Coverage

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. Two of these NCDs were for urine culture and serum iron studies tests. The rule was proposed in the March 10, 2000 edition of the *Federal Register* (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that specific tests were reasonable and necessary for certain medical indications. These decisions were evidence-based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled "ICD-9-CM Codes Covered by Medicare," and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled "ICD-9-CM Codes Denied," and lists diagnosis codes that are never covered by Medicare. The third list is entitled "ICD-9-CM Codes that do not Support Medical Necessity," and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary. We determined in the urine culture and serum iron studies NCDs that any ICD-9-CM code not listed in either of the ICD-9-CM covered or not covered sections would be categorized into this group that does not support medical necessity.

IV. Timeline of Recent Activities

As mentioned above, on March 10, 2000, CMS published a Notice of Proposed Rulemaking (NRPM) in the *Federal Register* (65 FR 13082). As an addendum to this NPRM, we proposed the 23 NCDs as negotiated by the rulemaking committee for public comment. On November 23, 2001, we published a final rule for coverage and administrative policies for clinical diagnostic laboratory services (66 FR 58788). The list of "ICD-9-CM Codes Covered by Medicare" associated with the urine culture and serum iron studies NCDs included the ICD-9-CM code V72.84, Pre-operative examination, unspecified.

On February 10, 2003 CMS received a letter requesting that we add ICD-9-CM codes V72.81 (Pre-operative cardiovascular examination), V72.82 (Pre-operative respiratory examination), and V72.83 (Other specified pre-operative examination) to the list of covered diagnoses for the PT and PTT NCDs. The basis of the request was that these codes were similar to ICD-9-CM code V72.84 that was listed as covered. We posted an announcement of this reconsideration on our coverage website on February 27, 2003. On September 29, 2003 we posted a decision on this request, stating that we were not adding the requested diagnoses and that we also would be removing code V72.84 from the list of covered diagnoses as it is a screening code. This change was implemented on January 1, 2004. We also noted in the decision memorandum that we would be reconsidering inclusion of the V72.84 code in the list of covered diagnoses for urine culture and serum iron studies.

On June 15, 2004, we announced in a tracking sheet posted on the Medicare coverage Internet site (cms.hhs.gov/mcd/viewtrackingsheet.asp?id=127) what we were considering the appropriateness of including ICD-9-CM codes V72.84 in the list of covered diagnoses for urine culture and serum iron studies. We solicited public comments during a 30-day period. At the end of the public comment period, July 15, 2005, we had received one comment. The commenter believes that urine cultures should be performed pre-operatively to ensure that the patient is infection free before undergoing any invasive procedure. The commenter did not identify any portion of the narrative indications of the NCD nor the Medicare statute that supported coverage of the screening procedure.

V. General Review Methodology

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. Thus, all of the codes in the covered code list must flow from the narrative indications of the NCD. We reiterated this position in the November 23, 2001 final rule (66 FR 58795) and in subsequent implementing instructions (Program Memorandum AB-02-110).

VI. CMS Analysis

The purpose of the coding analysis is to determine whether coverage of the codes in question is consistent with the narrative of the NCDs that were developed using evidence-based policies in the negotiated rulemaking process and published on November 23, 2001.

In the urine culture NCD, there is an expressed discussion of pre-operative assessment in the indications sections. Specifically, the urine culture NCD states the following:

"In surgical procedures involving major manipulations of the genitourinary tract, preoperative examination to detect occult infection may be indicated in selected cases (for example, prior to renal transplantation, manipulation or removal of kidney stones, or transurethral surgery of the bladder or prostate)."

The serum iron studies NCD includes the following narrative indication related to pre-operative use of the test:

"The following presentations are examples that may support the use of these studies for evaluating iron deficiency: ...preoperative autologous blood collection(s)."

Thus, while the narrative indications for urine culture and serum iron studies do reflect some pre-operative situation, they are not unspecified conditions. We do not believe that either of the above conditions would generally appropriately be coded as V72.84. Rather, specific codes related to these conditions exist. For example, most diagnoses that would give rise to a major manipulation of the genitourinary tract are included on the list of covered diagnoses. If a physician believes it is necessary to perform a urine culture to detect occult urinary tract infection in a patient for a disease that gives rise to a major manipulation that is not on the list, the appropriate way to address the situation is to submit the claim with justification. We do not believe it is appropriate to cover an unspecified pre-operative code to avoid this complication in bill processing.

Further, this language concerning pre-operative assessment in the urine culture and serum iron studies narratives must be read consistently with the general language in the November 23, 2001 final rule concerning screening tests. Medicare has historically interpreted the provisions of the Medicare statute in section 1862(a)(7) and 1862(a)(1)(A) to prohibit coverage of screening services. The final rule from November 23, 2001 has numerous references to the lack of coverage for services that are furnished in the absence of signs or symptoms of illness or injury. For example, every policy includes a "Reasons for Denial" section that states:

"Tests for screening purposes that are performed in the absence of signs, symptoms, complaints or personal history of disease or injury are not covered except as explicitly authorized by statute."

In addition, each NCD includes a coding guideline section indicating that: "Screening tests are performed when no specific sign, symptom, or diagnoses is present and the patient has not been exposed to a disease." Several other individual NCDs, such as the lipid NCD, include explicit statements regarding the exclusion of coverage for tests provided in the absence of signs or symptoms. In developing the NCDs for clinical laboratory services, we tried to be clear and consistent regarding Medicare's policy of excluding coverage of services furnished in the absence of signs, symptoms, and personal history of disease throughout the final rule and all instructions related to these NCDs.

Code V72.84 as an unspecified preoperative code is generally used only in the absence of signs, symptoms and history of disease or along with other more specific diagnoses. Thus, we believe this code is generally considered as an indicator of routine screening. We do not believe that it is consistent with the narrative of the urine culture and serum iron studies NCDs to provide routine pre-operative screening services for patients who demonstrate no signs, symptoms or past history of disease indicating that a urine culture or serum iron study might be beneficial.

In summary, the V72.84 code does not indicate an autologous blood collection or other indication of iron deficiency. In cases of major manipulations of the genitourinary tract, the disease causing the need for the surgery is likely to already be included in the list of covered diagnoses. Thus, we conclude that code V72.84 does not flow from the narrative indications of the NCDs in question.

The Committee developed these lists of codes with very little time for study and careful evaluation. The Committee was concerned with the possibility of errors in the NCDs and encouraged commenters to submit copies of medical literature supporting their recommendations for change (65 FR 13087). We believe that this expedited schedule may have lead to the inappropriate placement of V72.84 on the list of "ICD-9-CM Codes Covered by Medicare" for urine culture and serum iron studies.

Finally, we note also that use of code V72.84 (Unspecified pre-operative examination) is not technically appropriate for urine culture and serum iron studies since both are specific tests. We intend to remove code V72.84 from the lists of covered diagnoses in both NCDs in an upcoming quarterly update of the laboratory edit module, as we do not believe they appropriately flow from the indications contained in the NCDs.

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